To: Zipkin, Adam (Booker)
Subject: RE: TSCA reform principles doc
Thanks Adam -- and sorry today got away from me, and now I have to run out for something, but let's connect tomorrow?

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Friday, March 20, 2015 5:21 PM
To: Vaught, Laura
Subject: RE: TSCA reform principles doc
Hi Laura FYI Jim Jones did great at the hearing. Do you have a few minutes Monday am to talk follow up?

From: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
Sent: Tuesday, March 17, 2015 3:47 PM
To: Zipkin, Adam (Booker)
Subject: Re: TSCA reform principles doc
Give me 2 minutes to get back to my desk and then yes.

Sent from my iPhone

On Mar 17, 2015, at 3:45 PM, Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov> wrote:

> Laura any chance you could talk now? Otherwise I have a 4pm meeting and then open 4:30-5:30.
>
> **From:** Vaught, Laura [mailto:Vaught.Laura@epa.gov]
> **Sent:** Tuesday, March 17, 2015 2:59 PM
> **To:** Zipkin, Adam (Booker)
> **Subject:** RE: TSCA reform principles doc
> Sure.
>
> **From:** Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
> **Sent:** Tuesday, March 17, 2015 2:58 PM
> **To:** Vaught, Laura
> **Subject:** Re: TSCA reform principles doc
> Can u call my cell after your 3pm mtg 973.204.7917?
>
> ---
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> **From**: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
> **Sent**: Tuesday, March 17, 2015 02:48 PM
> **To**: Zipkin, Adam (Booker)
> **Subject**: RE: TSCA reform principles doc
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> Sounds good. I'm around until a little after 3 when I have to go to a meeting, but I don't think will take long.
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> **From:** Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
> **Sent:** Tuesday, March 17, 2015 2:38 PM
> **To:** Vaught, Laura
> **Subject:** Re: TSCA reform principles doc
> I will try u in 5 min
>
> ---
>
> **From**: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
> **Sent**: Tuesday, March 17, 2015 12:27 PM
> **To**: Zipkin, Adam (Booker)
> **Subject**: RE: TSCA reform principles doc
>
> Hi Adam -- happy to connect on these when you're free. My direct is 564-0304

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Tuesday, March 17, 2015 9:20 AM
To: Vaught, Laura
Subject: RE: TSCA reform principles doc

Laura good morning -- attached are draft questions. Could we do a call to discuss once you have a chance to review on your end? Thanks! Adam

From: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
Sent: Monday, March 16, 2015 11:17 AM
To: Zipkin, Adam (Booker)
Subject: FW: TSCA reform principles doc

Hi Adam – here are the Administration's TSCA principles that were announced in 2009.

Message

From: Vaught, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C30920BCB6214A91B7E3C1E7810C63E1-VAUGHT, LAURA]
Sent: 3/25/2015 8:26:37 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]
Subject: RE: TSCA reform principles doc

Adam - if you happen to be around and have a minute to touch base, give me a call at 564-0304

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Wednesday, March 25, 2015 12:05 PM
To: Vaught, Laura
Subject: RE: TSCA reform principles doc

Thanks!

From: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
Sent: Wednesday, March 25, 2015 12:00 PM
To: Zipkin, Adam (Booker)
Subject: Re: TSCA reform principles doc

Hi Adam - sorry it has been so hard to connect. Jim is on travel today/this week, but let me see what we can figure out.

Sent from my iPhone

On Mar 25, 2015, at 11:05 AM, Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov> wrote:

> Hi Laura. Attached is a draft red-line of the current Udall-Vitter bill that I am working on for my boss and other EPW Dems to present to Sens Udall/Vitter as containing the changes needed in order for these Senators to support the bill. Please treat as confidential. Things are moving quickly, is there any chance Mr. Jones and/or any other EPA staff could review and do a TA call with me this afternoon? The amount of changes are limited, and can be summarized as follows:
>
> 1. Preemption
>
> - Consistent with existing law, timing of preemption for High Priority Chemicals is amended to occur at the implementation date of EPA action on a chemical (current bill has high priority preemption starting as soon as EPA starts reviewing a high priority chemical, rather than when EPA finishes).
>
> 2. Co-enforcement
>
> - Consistent with existing law, bill is amended to allow states to enact and co-enforce identical laws (current bill does not allow).
>
> 3. Judicial Review
>
> - Bill is amended to allow full judicial review of chemicals that EPA designates as low priority (current bill only allows states to challenge).
>
> 4. Articles (i.e. consumer products)
>
> - Bill is amended to delete out this newly inserted section which Mr. Jones testified is inconsistent with statement of administration priorities.

5. Animal Testing

- Language is added to minimize animal testing where EPA Administrator determines scientifically reliable alternatives exist that would generate equivalent information.

6. Pre-emption of State Clean Air/Clean Water Laws

- Language is tweaked to try to make clear that this pre-emption should not occur.

From: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
Sent: Tuesday, March 24, 2015 11:13 AM
To: Zipkin, Adam (Booker)
Subject: RE: TSCA reform principles doc

My morning is a little crazy - anything this afternoon that works?

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Monday, March 23, 2015 8:47 PM
To: Vaught, Laura
Subject: RE: TSCA reform principles doc

Thanks Laura - I could do 10am or 11:30 if either of those work for you tmrw.

From: Vaught, Laura [mailto:Vaught.Laura@epa.gov]
Sent: Monday, March 23, 2015 5:24 PM
To: Zipkin, Adam (Booker)
Subject: RE: TSCA reform principles doc

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To: Zipkin, Adam (Booker)
Subject: FW: TSCA reform principles doc

Hi Adam - here are the Administration's TSCA principles that were announced in 2009.

Purpose: In the nature of a substitute.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the following:

"(2) REFORM.—This Act, including ~~It is the intent of Congress that~~ reforms ~~of this Act~~ in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures

is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances under which the Administrator determines a chemical substance is or may be manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

~~"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.~~

"(a~~b~~) Deadline.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(b~~c~~) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies, ~~and~~ procedures, and guidance described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall ~~describe the manner in which the Administrator shall~~ ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of

Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate,~~ existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act~~hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency~~.

"(e) Review.—Not later than 5 years after the date of enactment of this Act~~section~~, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this Act~~section~~, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In carrying out ~~making any decision with respect to a chemical substance under~~ sections 4, 4A, 5, and~~or~~ 6, the Administrator shall take into consideration information relating to ~~the hazards and exposures of~~ a chemical substance, including hazard and exposure information, under the conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—In establishing T~~t~~he policies and procedures ~~established~~ under paragraph (1), the Administrator shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) consult, as appropriate, ~~require the Administrator to consult~~ with the Director of the National Institute for Occupational Safety and Health with respect ~~prior~~ to any requirements to conduct ~~prescribing~~ epidemiologic studies of employees; and

"(D) with respect to any ~~prior to making a~~ request or ~~adopting a~~ requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—~~In establishing At a minimum,~~ the policies and procedures under this paragraph, the Administrator shall, at a minimum—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which ~~that~~ information submitted by interested individuals or entities will be evaluated;

"(ii) require that each draft and final safety assessment and safety determination of the Administrator include a description of—

"(I)(aa) to define the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, conditions of use of the chemical substance, and potentially exposed and susceptible populations that the Administrator ~~expects to~~ has considered in a safety assessment; and

"(bb) ~~to explain~~ the basis for the scope of the safety assessment and safety determination; ~~and~~

~~"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and~~

~~"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and~~

~~"(bb) to explain the basis for the consideration of those items;~~

"(II~~iii~~) ~~describe~~ the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use were ~~will be~~ considered, and ~~explain~~ the basis for that consideration ~~in the final safety assessment~~;

~~"(iv) require that each safety assessment and safety determination shall include—~~

"(III) ~~a description of~~ the weight of the scientific evidence of risk; and

"(IV~~I~~) ~~a summary of~~ the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

"(iii~~v~~) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(iv~~i~~) when relevant information is provided or otherwise made available to the Administrator, shall consider the extent of Federal regulation under other Federal laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank

R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft safety assessment for consideration by the Administrator.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), (e), and (g);

(2) by redesignating subsections ~~(e) and~~ (f) as subsections ~~(f) and (g), respectively~~;

~~(3) in subsection (f) (as so redesignated)—~~

~~(A) by striking "rule" each place it appears and inserting "rule, testing consent agreement, or order"~~;

~~(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and~~

~~(C) in paragraph (1)—~~

~~(i) in subparagraph (A)(v), by inserting ", without taking into account cost or other nonrisk factors" after "the environment"; and~~

~~(ii) in subparagraph (B), in the last sentence, by striking "rulemaking";~~

(34) in subsection (g) (as so redesignated)—

(A) in the first sentence—

(i) by striking "from cancer, gene mutations, or birth defects"; and

(ii) by inserting ", without taking into account cost or other nonrisk factors" before the period at the end; and

(B) by striking the last sentence; and

(45) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(~~gh~~), the Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test ~~data and~~ information for the chemical substance or mixture, including specific reference to any reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(5) The Administrator shall consider the recommendations of other federal agencies respecting the chemical substances and mixtures to which the Administrator should give priority consideration under this section.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an

order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies,

systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

"(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

"(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

"(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

"(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

"(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) subject to paragraph (3), persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the rule, testing consent agreement, or order; but

"(ii) before the period ending on the later of—

"(I) 5 years after the date referred to in clause (i); or

"(II) the last day of the period that begins on the date referred to in clause (i) and that is equal to the period that the Administrator determines was necessary to develop the information.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under

subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that no ~~a~~ person has complied ~~covered by the exemption has failed to comply~~ with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental

Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Prioritization Screening Process ~~Establishment~~ and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and ~~explicit~~ criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall ~~take into~~ consider~~ation~~ and publish an initial list of high-priority substances and low-priority substances; and

"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for th~~ose~~ high-priority substances identified under section 6(b).

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) PERSISTENCE AND BIOACCUMULATION.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as

practicable and not later than—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In implementing the prioritization screening process under ~~carrying out~~ paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In implementing the prioritization screening process under ~~carrying out~~ paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed

for all chemical ~~high-priority~~ substances not designated as a low priority.

"(III) ~~LOW-PRIORITY SUBSTANCES~~REPRIORTIZATION.—

"(aa) If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(bb) If a high-priority substance is subsequently designated as a low-priority substance, the Administrator shall remove that substance from the list of high-priority substances.

Commented [Z1]: Revised based on TA to clarify.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) except as provided under paragraph (2), not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—The Administrator shall keep current and publish and provide an opportunity for public comment on a list of chemical substances ~~that—~~

"(i) that are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process~~, including those chemical substances~~

"(ii) for which prioritization decisions have been postponed pursuant to

subsection (b)(5), including the basis for such postponementsdeferred; and

"(iii) that are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including persistence, bioaccumulation, and specific scientific classifications and designations by authoritative governmental entities;

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported pursuant to under a rule promulgated under pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—In implementing Tthe prioritization screening process developed under subsection (a), shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF REASONABLY AVAILABLE INFORMATION.—The prioritization screening decision regarding a chemical substance shall ~~integrate~~ consider any hazard and exposure information relating to the chemical substance that is reasonably available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard and significant exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard or significant exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the safety standard.

"(5) ~~DEFERRING~~ POSTPONING A DECISION.—If the Administrator determines that additional information is needed ~~required~~ to establish the priority of a chemical substance under this section, the Administrator may ~~defer~~ postpone a ~~the~~ prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

~~"(7) NOTICE AND COMMENT.—The Administrator shall—~~

~~"(A) publish, including in the Federal Register, the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and~~

~~"(B) provide 90 days for public comment.~~

"(7~~8~~) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the

Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(8[9]) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(9[10]) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(~~1~~1) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The rule promulgated under subsection (a) ~~prioritization screening process developed under subsection (a)~~ shall—

"(i) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance as an additional priority for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E);

"(ii) specify the information to be provided in such requests; and

"(iii) specify the criteria (including the criteria identified in subsection (a)(4)) that the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(B) PREFERENCE.—Subject to paragraph (2), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(C) EXCEPTIONS.—Chemical substances for which ~~R~~requests have been granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).

"(2) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) if a sufficient number of additional priority requests meet the requirements of paragraph (1), not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1);

"(B) the resources allocated to conducting safety assessments and safety

determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section; and

"(C) the number of additional priority requests stipulated under subparagraph (A) is in addition to the total number of high-priority chemicals identified under subsection (a)(2)(B).

"(3) ADDITIONAL REVIEW OF WORK PLAN CHEMICALS FOR SAFETY ASSESSMENT AND SAFETY DETERMINATION.—In the case of a request under paragraph (1) with respect to a chemical substance identified by the Administrator in the October 2014 Work Plan—

"(A) the 30-percent cap specified in paragraph (2)(A) shall not apply and the addition of Work Plan chemicals shall be at the discretion of the Administrator; and

"(B) notwithstanding paragraph (6), requests for additional Work Plan chemicals under this subsection shall be considered high-priority chemicals subject to section 18(b) but not subsection (a)(3)(A)(iii).

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to

appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices";

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "subsection (h)" and inserting "paragraph (3) and subsection (h)"; and

(ii) in the matter following subparagraph (B)—

(I) by striking "subsection (d)" and inserting "subsection (c)"; and

(II) by striking "and such person complies with any applicable requirement of subsection (b)"; and

(C) by adding at the end the following:

"(3) ARTICLE CONSIDERATION.—The Administrator may require the notification for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.";

(6) by redesignating subsections (c) and (d) as subsections (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by replacing "subsection (a)" with "subsection (b)";

(ii) by striking "or of data under subsection (b)";

(iii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iviii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make ~~any necessary~~ determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the

restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) ~~take into~~ consider~~ation~~ whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, ~~or of the chemical substance for a new use,~~ that does not conform to ~~is not in compliance with~~ the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is likely to meet the safety standard, reduce potential exposure to the substance to the maximum extent practicable.

~~"(E) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.~~

"(EF) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of

a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders submitted under this section or made by ~~of~~ the Administrator under this section; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "(a) or"; and

(ii) in subparagraph (A), by inserting ", without taking into account cost or other nonrisk factors" after "the environment";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY

DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate any necessary final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under this subsection, including ~~paragraphs (4) and (5) and~~ any deferral under subsection (c)(2), does not exceed 2 years.

"(b) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies, ~~and~~ procedures, and guidance required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—

Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

"(3) NOTICE OF EXISTING INFORMATION.—

"(A) IN GENERAL.—The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in safety assessments and safety determinations with the objective of increasing the efficiency of the safety assessments and safety determinations.

"(B) INCLUSION OF INFORMATION.—Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, and subject to section 18, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

"(ii) if the safety standard cannot be met with the application of other restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety

determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—

"(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

"(i) may apply to mixtures containing the chemical substance, as appropriate;

"(ii) shall include dates by which compliance is mandatory, which—

"(I) shall be as soon as practicable;

"(II) in the case of a ban or phase-out of the chemical substance, shall implement the ban or phase-out in as short a period as practicable; and

"(III) as determined by the Administrator, may vary for different affected persons; and

"(iii) shall exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk; and

"(iv) shall, in selecting among prohibitions and other restrictions, apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary to address the identified risks in order to determine that the chemical substance meets the safety standard.

"(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(D) DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with

respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban, ~~or~~ phase out, or ~~any~~ otherwise restrict ~~rule regarding,~~ the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the